Citation:

Lara JJ, Economou M, Wallace AM, Rumley A, Lowe G, Slater C, Caslake M, Sattar N, Lean ME. Benefits of salmon eating on traditional and novel vascular risk factors in young, non-obese healthy subjects. *Atherosclerosis*. 2007 Jul; 193(1): 213-221. Epub 2006 Oct 27.

PubMed ID: 17069820

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To test the hypothesis that oil-rich fish consumption improves coronary heart disease (CHD) risk factors.

Inclusion Criteria:

Healthy adults without obesity (BMI of 18.5 to 29.9kg/m^2).

Exclusion Criteria:

Subjects:

- With a previous diagnosis
- Taking any prescribed medication
- Taking fish oils supplements
- Following special diets.

Description of Study Protocol:

Recruitment

Subjects were recruited by local advertising at Glasgow University and the Glasgow Royal Infirmary between January and March 2004.

Design

Cross-over clinical trial.

Dietary Intake/Dietary Assessment Methodology

- Seven-day dietary record for the experimental time
- Scottish Dietary Target Monitor [a short version of food-frequency questionnaire (FFQ)] was used to assess the baseline habitual consumption.

Intervention

- *Experimental diet:* A standard diet (50% CHO, 35% protein, 15% fat) + 125g per day of oil-rich fish (salmon) for four weeks
- *Control diet:* A standard diet (50% CHO, 35% protein, 15% fat) without fish for four weeks.

Statistical Analysis

- GLM for repeated measurements was performed to compare treatments taking a significance level of 0.05
- Unadjusted results (mean±SD and mean differences with 95% CI), as well as adjusted results for the following are presented:
    - Age
    - Sex
    - Smoking status
    - Weight change
    - Dietary sodium
    - Fat intake
    - Use of salt at the table.

Data Collection Summary:

Timing of Measurements

Dietary intake in both experimental and controlled period (four weeks each).

Dependent Variables

- Body composition: Height, weight, waist circumference
- Blood pressure
- Fasting blood samples for Lipoproteins (Triglycerides, HDL, LDL and VLDL), plasma glucose, fatty acid, adiponectin, insulin, leptin, ICAM-1, plasma lipids, CRP, fibrinogen.

Independent Variables

Fish consumption.

Description of Actual Data Sample:

- *Initial N:* 48 (32 females, 16 males)
- *Attrition (final N):*
    - 48 for the experimental period
    - 41 completed the non-fish period
- *Age:*
    - 26.4±5.9 years for males
    - 29.1±8.6 years for women
- *Anthropometrics:*

- BMI
  - 23.1kg/m^2 for males
  - 23.2kg/m^2 for females
- Waist circumference
- 80.0cm for males
- 73.1cm for females
- *Location:* Glasgow, Scotland.

Summary of Results:

	Baseline (N=48)	After Salmon (N=48)	P-Value After Salmon (Baseline)	No Fish (N=41)	Mean Difference (95% CI) Salmon– No Fish	P-Value
Blood pressure						
SBP	113.7±0.7	109.9±9.9	0.003	114.7±8.8	-4.6 (-7.0, -2.1)	0.001
DBP	72.7±7.6	71.4±6.6	0.111	74.5±8.0	-3.0 (-5.0, -0.9)	0.007
MABP	86.4±7.5	84.3±6.6	0.021	87.7±7.2	-3.5 (-5.5, -1.6)	0.001
Triglycerides (mmol/L)	0.94±0.33	0.82±0.35	0.003	0.97±0.37	-0.13 (-0.25, -0.003)	0.04
VLDL (mmol/L)	0.42±0.15	0.37±0.15	0.003	0.44±0.17	-0.06 (-0.11, -0.002)	0.042
LDL (mmol/L)	2.51±0.66	2.46±0.70	0.501	2.48±0.64	-0.13 (-0.25, 0.001)	0.051
HDL (mmol/L)	1.38±0.30	1.49±0.33	0.001	1.33±0.78	0.08 (0.008, 0.16)	0.031
Total cholesterol/HDL(mmol/L)	3.24±0.86	3.01±0.88	<0.0001	3.30±0.78	-0.24 (-0.38, -0.11)	0.001
Adiponectin (mcg/ml)	6.81±3.82	8.01±4.22	0.022	7.74±4.33	0.55 (-0.41, 0.0001)	0.089

Note: MABP=[(DBP x 2) + SB]/3.

Mean difference were from analysis of variance (GLM) for repeated measurements adjusted for age, sex, BMI, smoking, weight change, dietary fat and sodium intake.

Other Findings

Salmon intake predict around a 25% reduction in CHD risk based on the PROCAM risk calculator.

Author Conclusion:

Daily consumption of salmon improves traditional risk predictors of CHD in non-obese subjects.

Reviewer Comments:

Study is well-designed and well-analyzed.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	N/A

2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	N/A
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No

5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	No
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	N/A
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes

	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		N/A
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		???
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	???